2. 510(k) SUMMARY

Sponsor Name:	TGM Medical, Inc. 5145 Golden Foothill Parkway, Suite 175 & 180 El Dorado Hills, CA 95762
510(k) Contact:	Dennis Crane Phone: 952.374.6012 / Fax: 952.374.6001 dennisc@emersonconsultants.com
Date Prepared:	08/08/2011
Trade Name:	MILESTONE Knee System (MKS)
Common Name:	Total knee prosthesis
Classification Name:	Knee joint patellofemorotibial metal/polymer/metal semi-constrained cemented prosthesis (21 CFR 888.3560, Class II device, Product Code JWH).
Review Panel:	Orthopedic Devices

Device Description:

The MILESTONE Knee System (MKS) is a primary, fixed-bearing, total knee system designed to replicate the natural anatomy of the knee in order to restore knee function. It was developed to preserve and utilize healthy ligamentous structures, and to restore stability to the knee.

The MKS incorporates femoral, tibial, and patellar components and all associated instrumentation needed for implantation. The femoral and tibial components are provided in left and right configurations. The femoral component is made from CoCr and is offered in a posterior stabilizing (PS) configuration. The tibial component comprises an asymmetric tibial baseplate made from CoCr alloy and an asymmetric PS tibial insert made from UHMWPE. The baseplate is designed to maximize metaphyseal bone coverage on the tibia. The baseplate employs a cruciate type keel to enhance implant fixation and torsion resistance. The tibial insert attaches to the baseplate via a mechanical locking mechanism. All MKS metallic components are available in uncoated variants for cemented use. The patellar component is an all-poly round patella made from UHMWPE, also intended for cemented use.

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Indications for Use:

The MILESTONE Knee System Primary Knee is designed as a system and is not intended for substitution of components from other systems.

A. Primary intervention of rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, or degenerative arthritis.
B. Failed osteotomy or unicompartmental replacements.
C. Replacement of unsatisfactory cemented or press-fit knee components when sufficient bone stock exists.

All MILESTONE Knee components are intended for cemented use only

Substantial Equivalence:

Technological Characteristics/Substantial Equivalence:
Consensus Orthopedics, Inc. (COI) licensed the previously cleared Consensus Knee System (CKS) posterior stabilized (PS), standard, uncoated femoral component (K954818), the CKS PS, reduced lateral profile (RLP), uncoated femoral component (K110950), the CKS PS tibial insert (K954818), the CKS uncoated, pegless, CoCr tibial baseplate (K001456), and the CKS round, all-poly patella (K932837) to TGM Medical for use as the MILESTONE Knee System (MKS). These predicate knee system components employ identical materials, design features, and indications as the respective MKS components. Therefore, the femoral, tibial, and patellar components used with the MKS are substantially equivalent to legally marketed predicate devices (Table 2.1).

Table 2.1: Legally marketed devices to which substantial equivalence is claimed.

510(k) Number	Trade Name	510(k) holder	510(k) Clearance
K932837	Consensus Knee System – Primary Knee	U.S. Medical Products, Inc.	09/27/1994*
K945589	Consensus® Knee Cobalt Chrome Nonporous Stemmed Tibial Baseplate	U.S. Medical Products, Inc.	05/31/1995*
K954818	Consensus Posterior Stabilized Knee	U.S. Medical Products, Inc.	05/22/1996*
K001456	Consensus® Knee System; Tibial Baseplate, Cast, CoCr/Ti Porous and CoCr Non-Porous	Hayes Medical, Inc.	08/07/2000**
K110950	Consensus Knee System: Reduced Lateral Profile (RLP) Posterior Stabilizing (PS) non-porous femoral component	Consensus Orthopedics	06/27/2011

Notes: *Cleared prior to the purchase of U.S. Medical Products by Hayes Medical in 1996. **Cleared prior to the change in company name from Hayes Medical to Consensus Orthopedics in 2008.

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Non-Clinical Performance Data:

The MILESTONE Knee System (MKS) implant components were evaluated using Failure Modes and Effects Analysis (FMEA) and biomechanical testing of its predicate CKS components. MKS components employ identical geometry and material characteristics as those employed by their respective predicate CKS components. Therefore, non-clinical bench testing and analyses were provided for these predicate components to validate the safety and effectiveness of the MKS. Further testing of MKS components was deemed unnecessary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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TGM Medical, Inc.
% Mr. Dennis Crane
Vice President, Clinical & Regulatory Services
Emerson Consultants, Inc.
12701 Whitewater Drive, Suite 120
Minnetonka, Minnesota 55343

Re: K112285
Trade/Device Name: MILESTONE Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: August 8, 2011
Received: August 9, 2011

Dear Mr. Crane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ed Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K112285

Device Name: MILESTONE Knee System

Indications for Use:

The MILESTONE Knee System Primary Knee is designed as a system and is not intended for substitution of components from other systems.

A. Primary intervention of rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, or degenerative arthritis.

B. Failed osteotomy or unicompartmental replacements.

C. Replacement of unsatisfactory cemented or press-fit knee components when sufficient bone stock exists.

All MILESTONE Knee components are intended for cemented use only.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) AND/OR Over the Counter Use ____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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